

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 24-34 are under examination in this application. Claims 24, 27, 28, and 32-34 have been amended. Claims 1-23, 25 and 29-31 have been canceled. New claim 35 has been added. No new matter has been added by this amendment. Support is found throughout the specification and from the pending claims.

As discussed per telephone with the Examiner on October 6, 2005, the amended claims set submitted herewith was filed previously with the United States Patent and Trademark Office on October 21, 2003 in a Preliminary Amendment. One copy of the October 21, 2003 Preliminary Amendment and the postcard stamped by the OIPE accompany this response.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendment of the claims, as presented herein, is not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, this amendment is made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendment should not give rise to any estoppel.

**II. THE OBJECTIONS ARE OVERCOME**

Formal objections to claim 30 were made as follows: in the first, claim 30 allegedly recited the term "MIS" twice; secondly, it was suggested that the acronym "MIS" be replaced with "Mullerian Inhibiting Substance".

Claim 30 has been canceled. Thus, the present objection is rendered moot. It is respectfully requested that the objection to the claim be withdrawn.

**III. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME**

Claims 24-30 and 32-34 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, it was alleged that the scope of the invention as claimed "encompasses recombinant genetic material that encodes any biological modifier, which is capable of inhibiting the excessive tissue proliferation caused [by]

any and all factors (genetic and environmental). Besides MIS the specification fails to disclose any other biological modifier via recombinant means that is capable of inhibiting the proliferation [of] cells caused [by] any etiology."

Claim 24 has been amended to specify that "the cells are genetically engineered to stably express Mullerian Inhibiting Substance (MIS)." Support for this amendment can be found in the specification, for example, on page 4, lines 23-27 and on page 5, lines 21-23. Accordingly, the alleged "huge genera" objected to in the Office Action is no longer recited in the claims. Claims 26-28 and 32-35 depend from claim 24 and, thus, carry the same limitation.

Claims 24-34 were rejected under 35 U.S.C. § 112, first paragraph, as the specification allegedly "does not enable any person skilled in the art to which it pertains...to make and use the invention commensurate in scope with these claims." Specifically, the Examiner stated that, "while being enabling for a cell-matrix structure for implantation comprising genetically engineered or primary Sertoli cells that express MIS that inhibits the tissue proliferation in ovarian cancer cell", the specification allegedly "does not reasonably provide enablement for a cell-matrix implant comprising genetically engineered or natural cells that express any and all biological modifiers that stop or regress excessive tissue proliferation in a tissue of any origin having any etiology."

As mentioned above, claim 24 has been amended to specify that "the cells are genetically engineered to stably express Mullerian Inhibiting Substance (MIS)". Accordingly, the person skilled in the art is no longer required to undertake "the identification and characterization of all biological modifiers (other than MIS) that would stop or regress excessive tissue proliferation in any type of tissue associated with any etiology." Claims 26-28 and 32-35 depend from claim 24 and, thus, carry the same limitation.

Reconsideration and withdrawal of the U.S.C. § 112, first paragraph rejections are earnestly solicited.

**IV. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME****Claims 24, 26-28, and 32-35 are not anticipated by Epstein**

The Office Action rejected claims 24-34 under 35 U.S.C. 102(b) as allegedly being anticipated by Epstein, *et al.* (*In Vitro Cell Dev Biol* 25(2):213-216, 1989). Applicants respectfully traverse the rejection.

Epstein describes a stainless steel mesh that supports growth of anchorage-dependent CHO fibroblasts containing an amplified genomic construct of the human gene for Mullerian Inhibiting Substance (MIS).

To form the basis of a proper rejection under 35 U.S.C. § 102(b), a cited reference must disclose each and every element of the rejected claim(s). *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). While Epstein describes a mesh supporting cells that produce MIS, the mesh is stainless steel. Amended claim 24 pending in the present application recites "A cell-matrix structure comprising a polymeric matrix and cells attached thereto..." Support for the amendment can be found in the specification, for example, on page 7, lines 15-17. Epstein does not contemplate a polymeric matrix and, therefore, fails to disclose each and every element of the claimed invention and should be removed from consideration as a reference under 35 U.S.C. § 102(b).

If an independent claim is not anticipated (i.e., is novel), then any claim depending therefrom is not anticipated. Claims 26-28 and 32-35 depend from claim 24. Accordingly, Epstein fails to anticipate claims 24, 26-28, and 32-35.

**Claims 24, 26-28, and 32-35 are not anticipated by Selawry.**

The Office Action rejected claims 24-34 under 35 U.S.C. 102(e) as allegedly being anticipated by Selawry (U.S. Patent No. 6,149,907). Applicants respectfully traverse the rejection.

Selawry describes a method of treating a disease resulting from a deficiency of a biological factor in a mammal comprising administering Sertoli cells and cells producing the biological factor. The biological factor is preferably a hormone. It is alleged that "Selawry teaches an implantable cell-matrix composition comprising Sertoli cells... Since Sertoli cells inherently expressed MIS... the cited art clearly anticipate the invention as claimed."

Amended claim 24 reads "A cell-matrix structure comprising a polymeric matrix and cells attached thereto in an amount sufficient to stop or regress abnormal cell or tissue growth

wherein the cells are genetically engineered to stably express Mullerian Inhibiting Substance (MIS)." Selawry does not contemplate cells genetically engineered to stably express MIS.

Because Selawry fails to disclose each and every element of the claimed invention, it should be removed from consideration as a reference under 35 U.S.C. § 102(e).


Reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

**CONCLUSION**

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application, reconsideration, and withdrawal of the objections to and rejections of the application, and prompt issuance of a Notice of Allowance are respectfully requested. No fee is believed to be due for entry and consideration of this paper, however, any fee occasioned by this paper may be charged, or overpayment credited to, Deposit Account No. 04-1105.

December 13, 2005

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Marina Heusch', written over a horizontal line.

Marina Heusch

Agent of Record

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